Group III: Claims 54 and 58, directed to a method of treatment of a disease; and

Group IV: Claims 57 and 59, directed to a computer algorithm.

Applicants traverse the Restriction Requirement for the reasons stated herein. Nevertheless, in order to be responsive to the Office Action, Applicants provisionally elect the invention of Group I, claims 1 to 27, for examination.

The Restriction Requirement is traversed with respect to the division of the claims of Group I from the claims of Groups II, III and IV.

Applicants respectfully point out that two separate requirements must be met in order for restriction to be proper. First, the inventions must be independent or distinct. Secondly, there must be a serious burden on the Examiner if restriction is required. See, for example, MPEP 803 (Restriction- When Proper), which states, in part:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, <u>even though it includes claims to independent or distinct inventions.</u>

Page 800-3; emphasis added.

Thus, it is not sufficient for an Examiner to assert that patentably distinct inventions are present in order to restrict an application. There also must be a serious burden on the Examiner to search and examine the entire application. For the reasons set forth below, Applicants respectfully submit that the burden of searching and examining the claims of Groups I through IV together has not been sufficiently established for the restriction to be proper.

Regarding Restriction of Group I from Group II

Applicants submit that, while the claims of Group I are patentably distinct from the claims of Group II, a thorough search of the elected claims of Group I, directed to a composition of compounds comprising at least two compounds that modulate the activity of one or more target molecules associated with one or more Single Nucleotide Polymorphisms (SNPs), likely will result in art relevant to examination of the claims of Group II, directed to methods of increasing overall treatment efficacy for a given patient population that include the step of selecting a combination of at least two of the compounds claimed in Group I. A thorough search of the elected compositions of Group I likely will result in art relevant to examination of the methods of Group II. Therefore, it would not present a serious burden for the Examiner to additionally search and examine the methods of Group II with the related subject matter of elected Group I.

Regarding Restriction of Group I from Group III

Applicants further submit that, while the claims of Group I are patentably distinct from the claims of Group III, a thorough search of the elected claims of Group I, directed to a composition of compounds comprising at least two compounds that modulate the activity of one or more target molecules associated with one or more Single Nucleotide Polymorphisms (SNPs), likely will result in art relevant to examination of the claims of Group III, directed to methods of treatment that include the step of administering at least one of the compounds claimed in Group I. A thorough search of the elected compositions of Group I likely will result in art relevant to examination of the methods of Group III. Therefore, it would not present a serious burden for the Examiner to additionally search and examine the methods of Group III with the related subject matter of elected Group I.

Regarding Restriction of Group I from Group IV

Applicants also submit that, while the claims of Group I are patentably distinct from the claims of Group IV, a thorough search of the elected claims of Group I, directed to a composition of compounds comprising at least two compounds that modulate the activity of one or more target molecules associated with one or more Single Nucleotide Polymorphisms (SNPs), likely will result in art relevant to examination of the claims of Group IV, directed to methods of determining the efficacy or toxicity of the compounds claimed in Group I. A thorough search of the elected compositions of Group I likely will result in art

relevant to examination of the methods of Group IV. Therefore, it would not present a serious burden for the Examiner to additionally search and examine the methods of Group IV with the related subject matter of elected Group I.

CONCLUSION

In the present case, given the similarity of the claims directed to the composition of compounds (Group I) and each of the method of increasing treatment by selecting at least two of the compounds (Group II), the method of treatment (Group III), and the method of determining efficacy (Group IV), Applicants assert that the Examiner would not be seriously burdened to search and examine the methods of Groups II, III and IV, with the claims of elected Group I. Accordingly, Applicants respectfully request that the Examiner reconsider the restriction of the claims of Group II, III and IV from the claims of Group I.

As set forth in the Remarks submitted herein, Applicants provisionally elect the claims of Group I. Examiner Chakrabarti is invited to call the undersigned attorney if there are any questions regarding this application.

Respectfully submitted,

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